



## **DEPARTMENT OF TRANSPORTATION**

### **Federal Motor Carrier Safety Administration**

**[Docket No. FMCSA-2021-0085]**

#### **Qualification of Drivers; Exemption Applications; Implantable Cardioverter Defibrillator (ICD)**

**AGENCY:** Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

**ACTION:** Notice of denials.

**SUMMARY:** FMCSA announces its decision to deny the applications from three individuals treated with an ICD who requested an exemption from the Federal Motor Carrier Safety Regulations (FMCSRs) prohibiting operation of a commercial motor vehicle (CMV) in interstate commerce by persons with a current clinical diagnosis of myocardial infarction, angina pectoris, coronary insufficiency, thrombosis, or any other cardiovascular disease of a variety known to be accompanied by syncope (transient loss of consciousness), dyspnea (shortness of breath), collapse, or congestive heart failure.

**FOR FURTHER INFORMATION CONTACT:** Ms. Christine A. Hydock, Chief, Medical Programs Division, (202) 366-4001, [fmcsamedical@dot.gov](mailto:fmcsamedical@dot.gov), FMCSA, DOT, 1200 New Jersey Avenue SE, Room W64-224, Washington, DC 20590-0001. Office hours are from 8:30 a.m. to 5 p.m., ET, Monday through Friday, except Federal holidays. If you have questions regarding viewing materials in the docket, contact Dockets Operations, (202) 366-9826.

## **SUPPLEMENTARY INFORMATION:**

### **I. Public Participation**

#### **A. Viewing Comments**

To view comments go to [www.regulations.gov](http://www.regulations.gov). Insert the docket number, FMCSA-2021-0085, in the keyword box, and click “Search.” Next, sort the results by “Posted (Newer-Older),” choose the first notice listed, and click “Browse Comments.” If you do not have access to the internet, you may view the docket online by visiting Dockets Operations in Room W12-140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590-0001, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366-9317 or (202) 366-9826 before visiting Dockets Operations.

#### **B. Privacy Act**

In accordance with 49 U.S.C. 31315(b)(6), DOT solicits comments from the public on the exemption request. DOT posts these comments, without edit, including any personal information the commenter provides, to [www.regulations.gov](http://www.regulations.gov), as described in the system of records notice (DOT/ALL-14 FDMS), which can be reviewed at [www.dot.gov/privacy](http://www.dot.gov/privacy).

### **II. Background**

On July 28, 2021, FMCSA published a *Federal Register* notice (86 FR 40677) announcing receipt of applications from three individuals treated with ICDs and requested comments from the public. The individuals requested an exemption from 49 CFR 391.41(b)(4) which prohibits operation of a CMV in interstate commerce by persons with a current clinical diagnosis of myocardial infarction, angina pectoris, coronary insufficiency, thrombosis, or any other cardiovascular disease of a variety known to be accompanied by syncope, dyspnea, collapse, or congestive heart failure. The public comment period closed on August 27, 2021, and eight comments were received.

FMCSA has evaluated the eligibility of the applicants and concluded that granting an exemption would not provide a level of safety that would be equivalent to, or greater than, the level of safety that would be obtained by complying with § 391.41(b)(4). A summary of each applicant's medical history related to their ICD exemption request was discussed in the July 28, 2021, *Federal Register* notice and will not be repeated here.

The Agency's decision regarding this exemption application is based on information from the Cardiovascular Medical Advisory Criteria, an April 2007 evidence report titled "Cardiovascular Disease and Commercial Motor Vehicle Driver Safety,"<sup>1</sup> and a December 2014 focused research report titled "Implantable Cardioverter Defibrillators and the Impact of a Shock in a Patient When Deployed." Copies of these reports are included in the docket.

FMCSA has published advisory criteria to assist medical examiners in determining whether drivers with certain medical conditions are qualified to operate a CMV in interstate commerce.<sup>2</sup> The advisory criteria for § 391.41(b)(4) indicates that coronary artery bypass surgery and pacemaker implantation are remedial procedures and thus, not medically disqualifying. ICDs are disqualifying due to risk of syncope.

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<sup>1</sup> The report is available on the internet at <https://rosap.nhtl.bts.gov/view/dot/16462>.

<sup>2</sup> These criteria may be found in 49 CFR part 391, APPENDIX A TO PART 391—MEDICAL ADVISORY CRITERIA, section D. Cardiovascular: § 391.41(b)(4), paragraph 4, which is available on the internet at <https://www.gpo.gov/fdsys/pkg/CFR-2015-title49-vol5/pdf/CFR-2015-title49-vol5-part391-appA.pdf>.

### **III. Discussion of Comments**

FMCSA received eight comments in this proceeding. Each of the eight comments supported Mr. Willard Drysdale's request for an ICD exemption. Mr. Drysdale's cardiologist stated that the chance of Mr. Drysdale experiencing an appropriate ICD discharge in the next 5 years is approximately 2 to 3 percent. Mr. Drysdale's cardiac rehabilitation program attested to his excellent progress with his rehabilitation and maintenance program and noted that he was asymptomatic during his rehabilitation. The Minnesota Department of Public Safety commented that it has no objection to Mr. Drysdale's exemption request. Four private citizens familiar with Mr. Drysdale, attested to his years of successful CMV driving experience, his good physical condition, and that his ICD has not discharged since it was implanted. One of the four private citizens also commented on each key question in the April 2007 and December 2014 ICD Evidence Reports regarding how they relate to Mr. Drysdale's circumstances and his ICD exemption request. Regarding the April 2007 report, the commenter's opinion was that for two of the most relevant studies, one was done in Canada where ICDs are not addressed, and that the other study did not find evidence supporting the contention that CMV drivers are at an increased risk for a crash in a motor vehicle. The commenter further opined that the study was very limited and therefore the commenter believed a more comprehensive and current study should be implemented. The commenter noted with respect to the key questions in the December 2014 report, that Mr. Drysdale's ICD had never discharged and offered that Mr. Drysdale would be willing to participate in a group study involving ICDs if granted an exemption. The applicant, Mr. Drysdale also commented and questioned why he is not permitted to cross state lines and go more than 150 miles with a CMV yet is permitted to drive across the State of Minnesota to deliver exempt agricultural commodities.

FMCSA evaluates each ICD exemption application received to determine whether an equivalent or greater level of safety can be achieved by the applicant. FMCSA acknowledges that the existing evidence is not conclusive concerning the impact of ICD treatment on the safe operation of CMVs and that more studies are needed prior to permitting individuals with ICDs to operate CMVs in interstate commerce. Regarding Mr. Drysdale's comments, the provisions referenced are handled under two separate sections in the FMCSRs. Specifically, transportation of agricultural commodities is handled under § 390.39 and does not require the driver to have a physical qualification examination, meet the physical qualification standards in § 391.41(b)(1) through (13), and receive a Medical Examiner's Certificate, Form MCSA-5876.

#### **IV. Basis for Exemption Determination**

Under 49 U.S.C. 31136(e) and 31315(b), FMCSA may grant an exemption from the FMCSRs for no longer than a 5-year period if it finds such exemption would likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved absent such exemption.

The Agency's decision regarding these exemption applications is based on an individualized assessment of the applicants' medical information, available medical and scientific data concerning ICDs, and any relevant public comments received.

In the case of persons with ICDs, the underlying condition for which the ICD was implanted places the individual at high risk for syncope or other unpredictable events known to result in gradual or sudden incapacitation. ICDs may discharge, which could result in loss of ability to safely control a CMV. The December 2014 focused research report referenced previously upholds the findings of the April 2007 report and indicates that the available scientific data on persons with ICDs and CMV driving does not support

that persons with ICDs who operate CMVs are able to meet an equal or greater level of safety.

## **V. Conclusion**

The Agency has determined that the available medical and scientific literature and research provides insufficient data to enable the Agency to conclude that granting these exemptions would achieve a level of safety equivalent to, or greater than, the level of safety maintained without the exemption. Therefore, the following three applicants have been denied an exemption from the physical qualification standards in § 391.41(b)(4):

Willard Drysdale (MN), William Edwards (NY), and Francisco Garcia (NJ)

The applicants have, prior to this notice, received a letter of final disposition regarding their exemption request. The decision letter fully outlined the basis for the denial and constitute final action by the Agency. The names of these individuals published in this notice summarizes the Agency's recent denials as required under 49 U.S.C. 31315(b)(4).

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Larry W. Minor,  
*Associate Administrator for Policy.*